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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/851,628	05/06/1997	CHARLES M. COHEN	JJJ-PO1-515	6154

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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 01/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	08/851,628	COHEN ET AL.	
	Examiner	Art Unit	
	David S Romeo	1647	

--The MAILING DATE of this communication app ars on the cov r sheet with th correspondence address --

THE REPLY FILED 21 December 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 4 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.
ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

(a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

(b) ☐ they raise the issue of new matter (see Note below);

(c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

(d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☒ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: *1-4,6-10,12,15-17,24,28,32 and 52-55*.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

David S Romeo
Primary Examiner
Art Unit: 1647

Continuation of 5. does NOT place the application in condition for allowance because: Claims 1-4, 6-10, 12, 15-17, 24, 28, 32, 52-55 re rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. atent No. 6,498,142. It is acknowledged that Applicants will consider filing a terminal disclaimer upon notification of allowable subject natter.

Applicants' argue that the examiner's reasoning on page 5, line 17, through page 6, line 2, is based on false premises and improperly onstrued logic. Applicants' arguments have been fully considered but they are not persuasive. The term "retinopathy" in the last Office ction is a misspelling and the Office action makes it clear that the tem should have been "nephropathy." The present claims define hronic diabetic nephropathy as "a chronic renal condition characterized by the progressive loss of renal function associated with the rogressive loss of functioning nephron units." The examiner maintains that all mammals, including those with chronic diabetic etinopathy and those without, are "at risk of chronic renal failure" no matter how infinitesimally small that risk may be. Further, the pecification at the paragraph bridging pages 11-12 defines subjects in, or at risk of chronic renal failure as including but not limited to ubjects afflicted with chronic diabetic nephropathy. The definition quoted by Applicants, i.e., "a subject is said to be in, or at risk of hronic renal failure, ... if the subject is reasonably expected to suffer a progressive loss of renal function associated with progressive oss of functioning nephron units," does not exclude all mammals being at risk of chronic renal failure because any mammal "is easonably expected to suffer a progressive loss of renal function associated with progressive loss of functioning nephron units."

Applicants argue that it is unclear how OP-1 improves function when no cited reference teaches the administration of OP-1 improves idney function. Applicant's arguments have been fully considered but they are not persuasive. Kuberasampath (BB, cited by Applicants) clearly teaches that the inflammatory response has been implicated as the cause of reduced tissue function or loss of tissue unction in diseases of the kidney and clearly teaches that glomerular nephritis and diabetes are believed to result in large part from nwanted acute inflammatory reaction and fibrosis. If an inflammatory response reduces tissue function, the reasonable expectation is hat inhibiting an inflammatory improves tissue function.

he rest of Applicants' arguments rely upon additional evidence that was not earlier presented and is not directed solely to issues which vere newly raised by the examiner in the final rejection. Therefore, these arguments will not be considered.